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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA
PHILADELPHIA DIVISION

UNITED STATES OF AMERICA; STATE OF FLORIDA; and STATE OF NEW YORK ex rel. JAYME MALETTERI	FILED MAY 29 2009 MICHAEL E. KUNZ, Clerk By Dep. Clerk	09 -2441
Plaintiffs,		**CASE NO.**
v.		
INSPIRE PHARMACEUTICALS, INC.		**FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**
Defendant.		

COMPLAINT UNDER THE *QUI TAM* PROVISIONS OF THE FALSE CLAIMS ACT

INTRODUCTION

1. This is a *qui tam* action brought by Relator, Jayme Maletteri, on behalf of the United States of America pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq* (the "FCA"), and on behalf of the State of Florida and the State of New York under their respective State False Claims Acts. The false claims at issue were caused to be made by the Defendant, Inspire Pharmaceuticals, Inc., by marketing and promoting the off-label use of the drug AzaSite in violation of federal and state statutes and regulations. Defendant's actions not only have caused monetary damages to government healthcare programs, but also have resulted in physical harm to patients and continue to threaten public safety.

2. The FCA provides that any person who knowingly submits or causes to be submitted

a false or fraudulent claim for payment or approval is liable for a civil penalty for each such claim, and three times the amount of the damages sustained by the government. The Florida and the New York False Claims Acts also provide for treble damages and civil penalties. The False Claims Act Statutes permit persons having information regarding false or fraudulent claims to bring an action on behalf of the government and to share in any recovery. The complaint must be filed under seal, without service on the defendant. The complaint remains under seal while the government conducts an investigation of the allegations in the complaint and determines whether to join the action.

3. Pursuant to the False Claims Acts, Relator seeks to recover on behalf of the United States, the State of Florida, and the State of New York, damages and civil penalties arising from government healthcare program payments for AzaSite prescriptions for unauthorized, off-label use. Defendant, by marketing and promoting AzaSite for unapproved off-label use, caused thousands of claims to be submitted to government healthcare programs for reimbursement of AzaSite prescriptions, when those prescriptions were not eligible for reimbursement.

JURISDICTION AND VENUE

4. This action arises under the False Claims Act, 31 U.S.C. § 3729 et seq. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, 31 U.S.C. § 3730, and 28 U.S.C. § 1345. This Court has jurisdiction over the State False Claims Act claims pursuant to 31 U.S.C. § 3732(b).

5. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process. Defendant can be found in, resides in, or has transacted business in the Eastern District of Pennsylvania.

6. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant

can be found in, resides in, or has transacted business in the Eastern District of Pennsylvania, and many of the alleged acts occurred in this District.

7. Relator is an "original source" and no allegation set forth in this Complaint is based on a public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or General Accounting Office report, hearing audit, or investigation, or from the news media.

THE PARTIES

8. Relator, Jayme Maletteri, is a resident of New Jersey and was employed as a sales representative by Defendant Inspire Pharmaceuticals Inc. ("Inspire") from May 2007 until May 2009. His principal responsibilities involved the promotion of AzaSite (azithromycin ophthalmic solution) and Elestat (epinastine HCl ophthalmic solution) in the states of Maryland, Delaware, New Jersey and Pennsylvania.

9. Defendant Inspire Pharmaceuticals Inc. (NASDQ symbol ISPH), a Delaware corporation headquartered at 4222 Emperor Boulevard, Suite 200, Durham, NC 27703, is a biopharmaceutical company focused on researching, developing and commercializing prescription pharmaceutical products for ophthalmic and pulmonary diseases. Its 2008 revenues were $70.5 million, but it reported an annual loss of $51.6 million. Its cash on-hand was reported at $73 million. In February 2007, Defendant Inspire entered into a license agreement with InSite Vision Incorporated pursuant to which it acquired exclusive rights to commercialize AzaSite. The license agreement granted Inspire exclusive rights to develop, make, use, market, commercialize and sell the products in the United States and Canada. Inspire currently employs approximately 90 territory managers which provide Inspire with national U.S. sales coverage for AzaSite.

FACTUAL ALLEGATIONS

10. Government healthcare programs tightly restrict the types and uses of drugs eligible for purchase using government funds. Federal regulations further prohibit drug companies from marketing practices that could lead to unnecessary or ineffective prescription of drugs. These regulations are intended to ensure that government healthcare program funds are only used to purchase drugs that have been determined to be safe and effective for treatment of specific conditions.

11. Relator alleges in this *qui tam* action that Defendant Inspire has undertaken a course of action that it knew would cause numerous violations of federal and state statutes and regulations relating to reimbursement for the drug AzaSite. Inspire does not write the prescriptions or provide AzaSite to the government healthcare programs. Rather, Inspire intentionally undertook a course of conduct that it knew would lead to the submission of thousands of ineligible claims for payment from government healthcare programs for AzaSite prescriptions. Many of the pharmacists and physicians submitting claims for AzaSite prescriptions were likely unaware that the claims were ineligible for reimbursement under government healthcare programs, but Inspire was fully aware that its actions would lead to the submission of false claims to the federal and state governments.

Regulatory Background

12. Pharmaceutical drugs cannot be sold in the United States until the Food and Drug Administration ("FDA") has concluded that a drug is safe and effective at specific dosages. The FDA-approved indications and dosages are set forth on an approved drug's label. Physicians may prescribe FDA-approved drugs for indications, or at dosages, that vary from those set forth

on the label, but drug companies are prohibited under the Food, Drug, and Cosmetic Act from marketing or promoting approved drugs for uses other than the approved uses set forth on the label. 21 U.S.C.§ 355(a) & (d). Distribution of prescription drugs for off-label uses is expressly prohibited. 21 U.S.C. § 331(d).

13. Federal law limits Medicaid reimbursement for prescription drugs to "covered outpatient drugs." 42 U.S.C. § 1396b(I)(10). Only drugs used for "medically accepted indications" qualify as covered outpatient drugs. 42 U.S.C. § 1396r-8(k)(3). Only an FDA-approved use, or one that is supported by express compendia set forth in the Medicaid statute, is a "medically accepted indication." 42 U.S.C. § 1396r-8(k)(6); § 1396r-8(g)(1)(B)(I).

14. Similarly, federal law limits Medicare reimbursement for "covered Part D drugs." 42 U.S.C. §1395w-102(e). In order for a prescription drug to be a "covered Part D drug" it must be used and sold in the United States and used for a "medically accepted indication" as defined by 42 U.S.C. §1396r-8(k)(6); 42 U.S.C. §1395w-102(e). As mentioned above, only an FDA approved use, or one that is supported by express compendia set forth in the federal statute is a "medically accepted indication." 42 U.S.C. §1396r-8(k)(6).

15. Federal anti-kickback laws, 42 U.S.C. § 1320a-7b(b), also regulate the marketing of pharmaceuticals to prevent overutilization of prescription drugs. Drug companies are prohibited from offering or paying remuneration, cash or otherwise, to induce physicians or others to recommend or prescribe drugs that may be paid for by federal programs such as Medicaid or Medicare. 42 U.S.C. § 1320a-7b(b). Improper and illegal inducements include payment of "research grants," paying physicians for "studies," or any payments that are based on the volume of prescriptions written.

Inspires's Marketing of Azasite for Off-label Use

16. Relator's qui tam allegations involve the promotion of AzaSite which accounts for more than one-third of Inspire's revenues and generated more than $10 million in sales in the first quarter of 2009. AzaSite was approved by the FDA in April 2007, for the treatment of bacterial conjunctivitis in adults and children one year of age and older. Bacterial conjunctivitis (pink eye) is the only FDA approved indication for AzaSite. A 2.5 ml. container of AzaSite costs less than ten-cents to produce and retails for more than $80.

17. Based on Relator's knowledge, AzaSite is currently listed on the formularies of 90% of Medicare part D plans; is reimbursable by the Federal Employees Health Benefits program (FEHB); is reimbursable by Tricare; and is listed on the formularies of thirty-two state Medicaid plans including California, New York, Texas and Florida. Relator believes more than 75% of all AzaSite sales are reimbursed by government health care plans.

18. Inspire launched AzaSite in August 2007 and, since 90% of bacterial conjunctivitis afflicts young children, the company's call-plans initially targeted pediatricians and primary care physicians. Bacterial conjunctivitis usually resolves itself within a week, with or without treatment. AzaSite is a macrolide which does not kill bacteria, but rather inhibits its growth. The product does not necessarily reduce the recovery time for a conjunctivitis infection, but may render the user less contagious. Just months after the launch of AzaSite, it was evident the targeted physicians were not prescribing the product and initial sales were dismal.

19. In October 2007, Relator, and other sales representatives, were summoned to an emergency meeting at Newark, NJ to review AzaSite sales data. The meeting was presided over by: Mark Menzies, Inspire's national sales director; Sandy Klein, the eastern region sales

manager; Eric Powers, the northeastern region sales manager and Dr. Favetta, a New Jersey ophthalmologist who is a paid-consultant for Inspire. The data showed the greatest number of AzaSite prescriptions were being written by ophthalmologists for the treatment of blepharitis. A decision was reached at the meeting to no longer target pediatricians and primary care physicians for sales calls, but rather ophthalmologists.

20. Blepharitis is an inflammation of the eyelids causing red, irritated, itchy eyelids and the formation of dandruff-like scales on the eyelashes. It is a common eye disorder caused by either bacteria or a skin condition. It is not contagious and does not cause permanent damage to eyesight. Without treatment, it usually resolves itself within a week. According to Mr. Maletteri, there are no indicated treatments for blepharitis, but for more than sixty-years, the standard treatment has been the application of a bactericidal ointment, such as Bacitracin, to the affected area. Unlike macrolides, such as AzaSite, bactericides kill bacteria. Although anyone can contract blepharitis, Relator has learned that most patients diagnosed with this condition are elderly and covered by government healthcare plans.

21. Relator attended a national sales convention at Las Vegas in February 2008 at which Inspire's vice-president of sales, Jerry St. Peter announced "We are going to take the blepharitis market by storm!" He advised that sales representatives would now concentrate on ophthalmologists and allergists, the physicians who primarily treat blepharitis.

22. In the months following the convention, Inspire paid a number of physicians and researchers to produce studies showing the efficacy of AzaSite for the treatment of blepharitis and a number of other eye conditions. Sales representatives were required to create "Plans of Attack" which targeted physicians writing the highest number of AzaSite prescriptions for

recruitment as AzaSite presenters who were paid $1,000 for viewing an on-line instructional video, or facilitators who were paid $250 to view the video. Presenters and facilitators received additional training, paid for by Inspire, at various hotels. Mr. St. Peter bragged of taking high-prescribing physicians to his box at Dallas Cowboy football games. Inspire paid these kickbacks to physicians as part of its off-label marketing scheme.

23. Sales representatives began distributing Inspire literature showing AzaSite's potential use for eye conditions other than conjunctivitis and touted AzaSite for the treatment of bletharitis, chalazions (styes), pterygiums (corneal growths), corneal abrasions and acne rosacea as well as for use as a pre-operative treatment for various eye procedures such as Lasik treatment, corneal transplants and intravitreal injections. During this period of time, Relator was cautioned by Ms. Klein to use careful wording in preparing physician call notes to avoid accusations of off-label promotion.

24. Recently, Inspire sales representatives began targeting optometrists for AzaSite sales calls at which the optometrists are educated regarding the symptoms of blepharitis and the efficacy of AzaSite for its treatment. In this manner, optometrists can enhance their routine eye exam fees while increasing the demand for AzaSite.

25. In the summer of 2008, one of Relator's top prescription writers, Dr. John Butler of Salisbury, MD, began using AzaSite, instead of a bactericide, as a pre-op medication prior to performing intravitreal eye injections on patients suffering from macular degeneration. One of Dr. Butler's patients treated in this manner developed endopthamitis, a severe bacterial infection that resulted in blindness in one of the patient's eyes. Dr. Butler confided to Relator that he had

been performing intravitreal procedures for more than fifteen-years and this was the first time any of his patients contracted endopthamitis. Dr. Butler reported this occurrence to the FDA.

26. Relator also heard that a Philadelphia physician named Dr. Chaudry (phonetic) used AzaSite as a pre-operative treatment for a Lasik patient who later contracted endopthamitis.

27. At the February 2009 national sales meeting in Las Vegas, Relator raised the issue of off-label promotion of AzaSite in front of a number of attendees, including Sandy Klein. Ms. Klein severely reprimanded him for publicly discussing a sensitive topic. She told him in the future, he should "keep his mouth shut and learn to play the game or leave the company." Relator continued to investigate Inspires's off-label promotion of AzaSite, and on May 21, 2009, Ms. Klein terminated Relator's employment with Inspire.

False Claims

28. Inspire knows that a substantial amount of the prescriptions for AzaSite have been and continue to be paid for by government healthcare programs, including Medicare, Medicaid, Tricare and FEHB, throughout the United States.

29. Physicians and pharmacists participating in the Medicaid program are required to sign a provider agreement with their resident state. These agreements require providers to comply with all Medicaid requirements. In the state of Florida, for example, Fla. Stat. § 409.907 governs Medicaid provider agreements and states that each "provider agreement shall require the provider to comply fully with all state and federal laws pertaining to the Medicaid program." Most states also require providers to certify that the provider is in compliance with all Medicaid requirements. Even in states without a certification requirement, all providers' participation in the Medicaid program is conditioned on compliance with all state and federal statutes and

regulations.

30. Typically, claims for the payment of off-label AzaSite prescriptions are submitted to government healthcare programs by the pharmacists who fill the patients' prescriptions. The pharmacist filling the prescription usually does not have knowledge as to whether the prescription is on-label or off-label. As a result, a pharmacist generally would not know whether the prescription is for a medically acceptable use and, accordingly, whether the prescription is under the circumstances a covered outpatient drug.

31. Even so, because off-label prescriptions are not eligible for reimbursement under government healthcare programs, submission of a claim for reimbursement to one of these programs for an off-label prescription is a false claim under the False Claims Act, 31 U.S.C. § 3729. The submission of Medicaid claims for off-label AzaSite prescriptions also violates the Florida False Claims Act and the New York False Claims Act. Because liability under these false claims act statutes arises for any person who knowingly causes a false claim to be submitted, Inspire is liable for the false claims it caused to be submitted by physicians or pharmacists as a result of Inspire's off-label marketing practices.

32. Inspire knows that off-label prescriptions for AzaSite are not eligible for reimbursement under government healthcare programs such as Medicare, Medicaid, Tricare, and FEHB. Nevertheless, Inspire knowingly and intentionally sought to increase the number of off-label prescriptions for AzaSite. Without Inspire's efforts to encourage and solicit providers to prescribe AzaSite for off-label uses, most of the ineligible claims for payment of off-label AzaSite prescriptions would not have been filed.

COUNT I

Violation of False Claims Act, 31 U.S.C. § 3729(a)
prior to and after the amendments enacted on May 20, 2009

33. Relator realleges and incorporates by reference the allegations of paragraphs 1-32 of this complaint.

34. This count sets forth claims for treble damages and forfeitures under the federal False Claims Act, 31 U.S.C. §§ 3729-3732.

35. Through the acts described above, Defendant and its agents and employees knowingly caused to be presented false and/or fraudulent claims, records, and statements in order to get government healthcare programs, including but not limited to Medicare, Medicaid, Tricare and FEHB, to pay for off-label AzaSite prescriptions.

36. Under the False Claims Act 31 U.S.C. § 3729(a) in effect prior to May 20, 2009, Defendant has violated:

(a) 31 U.S.C. § 3729(a)(1) by knowingly presenting, or causing to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(b) 31 U.S.C. § 3729(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; and/or

(c) 31 U.S.C. § 3729(a)(3) by conspiring to defraud the Government by getting a false or fraudulent claim allowed or paid.

37. Under the False Claims Act 31 U.S.C. § 3729(a)(1) as amended on May 20, 2009, Defendant has violated:

(a) 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;

(b) 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and/or

(c) 31 U.S.C. § 3729(a)(1)(C) by conspiring to commit a violation of subparagraph (A) or (B).

38. The United States, unaware of the falsity of the claims, approved, paid, and participated in payments made by the United States for claims that otherwise would not have been allowed.

39. By reason of Defendant's false claims, the United States has been damaged and possibly continues to be damaged.

COUNT II

Violation of Florida False Claims Act, Fla. Stat. §68.082(2)

40. Relator realleges and incorporates by reference the allegations of paragraphs 1-32 of this complaint.

41. This count sets forth claims for treble damages and forfeitures under the Florida False Claims Act.

42. Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the Florida Medicaid program false and/or fraudulent claims, records, and statements in order to get Medicaid to pay for off-label AzaSite prescriptions..

43. Defendant has knowingly violated:

(a) Fla. Stat. §68.082(2)(a) by knowingly presenting, or causing to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;

(b) Fla. Stat. §68.082(2)(b) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency; and/or

(c) Fla. Stat. §68.082(2)(c) by conspiring to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

44. The State of Florida unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of Florida for claims that otherwise would not have been allowed.

45. By reason of Defendant's fraudulent activities, the State of Florida has been damaged, and possibly continues to be damaged.

COUNT III

Violation of New York False Claims Act, N.Y. State Fin. Law § 189.1

46. Relator realleges and incorporates by reference the allegations of paragraphs 1-32 of this complaint.

47. This count sets forth claims for treble damages and forfeitures under the New York False Claims Act.

48. Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the New York Medicaid program false and/or fraudulent claims, records, and statements in order to get Medicaid to pay for off-label AzaSite prescriptions..

49. Defendant has knowingly violated:

(a) N.Y. State Fin. Law § 189.1(a) by knowingly presenting, or causing to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

(b) N.Y. State Fin. Law § 189.1(b) by knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government; and/or

(c) N.Y. State Fin. Law § 189.1(c) by conspiring to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

50. The State of New York unaware of the falsity of the claims, approved, paid, and participated in payments made by the State of New York for claims that otherwise would not have been allowed.

51. By reason of Defendant's fraudulent activities, the State of New York has been damaged, and possibly continues to be damaged.

COUNT IV

Defendants' Violation of 31 U.S.C. § 3730(h)

52. Relator realleges and incorporates by reference the allegations of paragraphs 1-32 of this complaint.

53. In violation of the False Claims Act § 3730(h), Defendant discriminated and took negative employment actions against Relator as a result of lawful actions taken by Relator in furtherance of his qui tam action and of efforts to stop Defendant's false claims act violations.

54. Defendant terminated Relator's employment due to Relator's investigation of Defendant's submission of false claims to government healthcare programs.

55. As a result of Defendant's retaliatory and discriminatory conduct, Relator has suffered damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff/Relator requests that judgment be entered against Defendant, ordering that:

a. Defendant cease and desist from violating the Federal False Claims Act; the Florida False Claims Act; and the New York False Claims Act;

b. Defendant pay an amount equal to three times the amount of damages the United States, the State of Florida, and the State of New York, have sustained because of Defendant's actions;

c. Defendant pay the maximum civil penalties allowable to be imposed for each false or fraudulent claim presented to the United States, the State of Florida, and the State of New York;

d. Plaintiff/Relator be awarded the maximum amount allowed pursuant the Federal False Claims Act, the Florida False Claims Act, and the New York False Claims Act;

e. Relator be awarded all damages available pursuant to 31 U.S.C. § 3730(h) as a result of Defendant's retaliation against Relator, including but not limited to 2 times the amount

of back pay, interest on the back pay, and compensation for any special damages as a result of the discrimination, including damages for emotional distress;

f. Plaintiff/Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs; and

g. United States and Plaintiff/Relator be granted all such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Relator on behalf of himself, the United States, the State of Florida and the State of New York, hereby demands a trial by jury.

Dated this 19th day of May, 2009.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been furnished by Certified Mail, Return Receipt Requested, this 29th day of May, 2009 to the following:

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